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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/155,605      | 09/29/1998  | TOM DE VRINGER       | 98.554              | 8895             |

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/155,605

Applicant(s)

Vringer

Examiner

Gollamudi Kishore

Art Unit

1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 4, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-37 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 24 6) ☐ Other:

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### DETAILED ACTION

The request for the extension of time, filing under 1.114 and the preliminary amendment dated 4-4-03 are acknowledged.

Claims included in the prosecution are 1-17 and 19-37.

#### *Claim Rejections - 35 U.S.C. § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-17 and 19-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 521 562 in view of EP 0 678 295, EP 0159237, GB 2002319, JP 05194253 by themselves or in combination.

EP 0521 562 teaches instant reverse vesicles containing sucrose fatty acid esters (note the abstract, Examples and claims). What this reference lacks is the teachings of dehydration of these vesicles to obtain a powder.

EP 0678 295 teaches that vesicular preparations can be lyophilized to form powders (note Example 1 and claims 1 and 7).

EP 0159237 teaches that emulsions (micelles) can be freeze-dried to form powders which are easier to handle than emulsions (note the abstract).



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**GB teaches that dehydration of lipid vesicles (liposomes) to prepare a stable powder which can be stored for longer periods of time (note the abstract).**

**JP 05194253 teaches the preparation of a powder of reverse micelles containing a surfactant (note the abstract).**

**The removal of solvent from the vesicles of EP 562 to form powders would have been obvious to one of ordinary skill in the art since EP 295, 237 and GB each teach that vesicular preparations can be dehydrated and because of the advantages of powders compared to liquids taught by EP 237 and GB; one skilled in the art would be motivated to dehydrate the vesicles of EP 562 with the expectation of obtaining similar powders. One of ordinary skill in the art would be motivated further to dehydrate the reverse micelles containing surfactants to prepare a powder since JP (253) teaches that powders of reverse micelles can be prepared.**

**Applicant's arguments based on the amendment adding the limitation that when the powder when dispersed in a biodegradable oil, the percent yield of the reversed vesicles is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil are not found to be persuasive since the prior art does not suggest the use of biodegradable oil in the preparation of vesicles. A careful examination of EP (562) indicates the use of a synthetic oil just as in instant application. Therefore, it is unclear as to how this limitation would overcome the rejection based on EP reference and how the findings are considered as unexpected. In summary:- the prior art of record clearly**

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indicates the knowledge in the art of preparing the reverse vesicles and the preparation of powders by dehydrating either micelles or vesicles, and one would be motivated to remove the solvent from reverse vesicles of EP 562 to prepare powders with a reasonable expectation of success.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**

  
**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**April 22, 2003**